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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	10/790,027	Confirmation No.	Unassigned
Applicant	John A. GIORDANO et al.		
Filed	2 March 2004		
TC/Art Unit	Unassigned		
Examiner	Unassigned		
Docket No.	48508-00014		
Customer No.	23767		

PATENT OFFICE FEE TRANSMITTAL LETTER

Commissioner for Patents
Alexandria, VA 22313

Sir:

The following fees are enclosed in connection with the filing of the attached papers:

Petition Filing Fee.....$130.00

It is not believed that any further fees are due in connection with the filing of the attached papers. However, the Commissioner is authorized to charge any underpayment or credit any overpayment of fees to the undersigned's deposit account no. 50-1067.

Respectfully submitted,

22 March 2004

Guido J. Galvez
Reg. No. 52,933

Preston Gates Ellis & Rouvelas Meeds LLP
1735 New York Avenue NW, Suite 500
Washington, DC 20006
Telephone : (202) 628-1700
Facsimile : (202) 331-1024

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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STATEMENT IN SUPPORT OF PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102 AND M.P.E.P. § 708.02(II)

Commissioner for Patents
Alexandria, VA 22313

Sir:

Pursuant to M.P.E.P. § 708.02 (II), and in addition to the Petition To Make Special filed concurrently herewith, the undersigned hereby states:

1. That there is an infringing product actually on the market. *See* copy of Product Package and Label, attached as Exhibit A.

2. That a rigid comparison of the alleged infringing product with the claims of the present application has been made.

3. That, in my opinion, some of the claims are unquestionably infringed.

4. That I have caused to be made a careful and thorough search of the prior art.

5. That the results of that prior art search are provided in the concurrently submitted Information Disclosure Statement and associated PTO/SB/08A, or were provided in the previously submitted Information Disclosure Statement and associated PTO/SB/08A.

All statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Respectfully submitted,

22 March 2004

Guido J. Galvez
Reg. No. 52,933

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1735 New York Ave., N.W.
Washington, DC 20006
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NDC 64980-120-01

Rising

Natafolic™-OB

PRENATAL

MULTI-VITAMIN
MULTI-MINERAL
SUPPLEMENT

RX ONLY

Manufactured for:
RISING PHARMACEUTICALS, INC.
Paramus, NJ 07652

Manufactured by:
Contract Pharmacal Corp.
Hauppauge, NY 11788

100 CAPLETS 10 X 10 UNIT DOSE PACK

Indications and Uses

Natafolic™-OB is indicated to provide vitamin and mineral supplementation throughout pregnancy and during the postnatal period for the lactating and non-lactating mother. It is also useful for improving the nutritional status prior to conception.

Natafolic™-OB: Contains 1 mg. folic acid, which is very important in the development of the baby's spinal column during a specific period of time. Women are advised to start taking folate supplementation several weeks before conception and to continue taking them through the first 12 weeks of pregnancy, or longer. It is recommended that all women of childbearing years take folic acid supplementation.

Contraindications

Folic acid (pteroylglutamic acid) is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid. Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver. Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (Vitamin B-12).

Warnings

Pernicious anemia should be ruled out before starting treatment. While folic acid corrects the blood picture of pernicious anemia, it does not ameliorate the attendant neurologic involvement.

Resistance to treatment may be due to depressed hematopoiesis, alcoholism, the present of anti-metabolic drugs, and to deficiencies of vitamins.

Prolonged use of iron salts may produce iron storage disease.

100 CAPLETS 10 X 10 UNIT DOSE PACK

...actions

...olic acid (pteroylglutamic acid) and Vitamin B-12 microbiological blood assays are invalidated by the administration of most antibiotics, methotrexate, and pyrimethamine. Folic acid (pteroylglutamic acid) is not effective reversing the toxic effects of methotrexate. Folinic acid (5-formyltetrahydrofolic acid) must be used in that situation. Black tarry stools may be due to either occult GI bleeding or iron therapy or both.

Folic acid may partially correct the hematological damage due to Vitamin B-12 deficiency of pernicious anemia, while the associated neurological damage progresses. In rare instances, allergic sensitization has been reported following both oral and parenteral administration of folic acid.

Supplementation of the diet by milk or other dietary sources of calcium may be advisable.

Adverse Reactions

Allergic sensitivity reactions and gastrointestinal disturbances may occur.

Dosage and Administration

Before, during and after pregnancy, one caplet daily, or as directed by a physician.

How Supplied

Natafolic™-OB is available as a light blue caplet, imprinted "RIS 120". Available in Box of Unit-Dose pack of 100 (10 x 10).

Rx Only

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Store at 20° - 25°C (68° - 77°F); excursions to 15° - 30°C (59° - 86°F).

WARNING: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

100 CAPLETS 10 X 10 UNIT DOSE PACK

Rising **Natafolic™-OB Prenatal**

One caplet daily provides:

	Amount Per Caplet
Vitamin A (Beta Carotene)	2700 I.U.
Vitamin C (Ascorbic Acid)	70 mg.
Vitamin D-3 (Cholecalciferol)	400 I.U.
Vitamin E (dl-Alpha Tocopheryl Acetate)	30 I.U.
Vitamin B-1 (Thiamine Mononitrate)	1.5 mg.
Vitamin B-2 (Riboflavin)	1.6 mg.
Niacin (Niacinamide)	18 mg.
Vitamin B-6 (Pyridoxine HCl)	2.5 mg.
Folic Acid	1 mg.
Vitamin B-12 (Cyanocobalamin)	12 mcg.
Calcium (Calcium Carbonate)	100 mg.
Iron (Ferrous Fumarate)	65 mg.
Magnesium (Magnesium Oxide)	28 mg.
Zinc (Zinc Oxide)	25 mg.
Copper (Cupric Oxide)	2 mg.

Other Ingredients: Acacia, Ascorbyl Palmitate, Croscarmellose Sodium, Dicalcium Phosphate, FD&C Blue #1 Lake, FD&C Yellow #5 Lake*, Gelatin, Hydroxypropylmethylcellulose, Magnesium Silicate, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Mineral Oil, Polyethylene Glycol, Polyvinylpyrrolidone, Silica, Sodium Ascorbate, Starch, Stearic Acid, Sucrose, and Titanium Dioxide.

*Contains FD&C Yellow #5 Lake (Tartrazine) as a color additive.

WARNING: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

Rising

NDC 64980-120-01

Natafolic™-OB

PRENATAL

10 X 10 Unit Dose Pack
100 Caplets

MULTI-VITAMIN
MULTI-MINERAL
SUPPLEMENT

USE 64980 12001 2

LOT # 03875
EXP 7/05